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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for all pre-mixes for medicated feedingstuff containing 40 g, 100 g or 200 g tilmicosin per kg pre-mix and administered to rabbits

International non-proprietary name (inn): tilmicosin

Background information

Tilmicosin is a semi-synthetic antibiotic of the macrolide group. The pre-mixes for medicated feedingstuffs containing 40 g, 100 g or 200 g of tilmicosin per kg pre-mix, are veterinary medicinal products which are indicated in pigs and rabbits for the prevention and treatment of respiratory diseases caused by microorganisms susceptible to tilmicosin.

On 8 April 2011, the European Commission presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding all pre-mixes for medicated feedingstuffs containing 40 g, 100 g or 200 g tilmicosin per kg premix and administered to rabbits. The CVMP was requested to give its opinion regarding the recommended dose and inclusion rates in feed for these veterinary medicinal products administered to rabbits.

The referral started on 5 May 2011. The Committee appointed Dr Cristina Muñoz Madero as rapporteur and Dr Petras Mačiulskis as co-rapporteur. Written explanations were provided by the marketing authorisation holders on 31 August 2011 and 20 January 2012.

Based on the evaluation of the currently available data, the CVMP considered that overall benefit-risk profile for these products remains positive subject to recommended changes of the product information and conditions affecting the marketing authorisations for all pre-mixes for medicated feedingstuff containing 40 g, 100 g or 200 g tilmicosin per kg pre-mix and administered to rabbits. Therefore, the

[1] Article 35 of Directive 2001/82/EC, as amended

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Committee adopted a positive opinion on 7 March 2012, recommending variations to the terms of the marketing authorisations for all pre-mixes for medicated feedingstuffs containing 40 g, 100 g or 200 g tilmicosin per kg pre-mix and administered to rabbits.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summary of product characteristics, labelling in Annex III and the conditions of the marketing authorisations in Annex IV.

The final opinion was converted into a Decision by the European Commission on 14 June 2012.